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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,138	01/23/2001	Marc Alizon	2356.0010-04	2082

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WASHINGTON, DC 20005

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/767,138

Applicant(s)

ALIZON ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-64 is/are pending in the application.
- 4a) Of the above claim(s) 23-34 and 41-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**Response to Amendment**

***Status of the Claims***

1. Acknowledgement is hereby made of receipt and entry of the amendment filed 25 August, 2003, wherein claim 35 was amended. This application contains claims 23-34 and 41-64 drawn to an invention non-elected with traverse. A complete response to the  
5 final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01). Claims 35-40 are currently under examination.

***Information Disclosure Statement***

10 2. The information disclosure statement filed 25 August, 2003, has been placed in the application file and the information referred to therein has been considered.

***35 U.S.C. § 112, First Paragraph***

15 3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 4. Claims 35-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In  
30 re Rasmussen, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In re Wertheim, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims have been amended to recite purified HIV-1<sub>ELI</sub> envelope

variants that differ from a number of prototypical HIV-1 isolates (e.g., IIIB, BRU, or ARV-2) by at least one amino acid residue wherein said residues are selected from a specific group of 16 different amino acids. As previously set forth, the disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. However, the disclosure clearly fails to provide adequate support for the other claimed limitations. The disclosure fails to identify other viruses with the recited characteristics. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants submit that the disclosure provides an adequate written description of the claimed invention. This argument is not persuasive for the reasons set forth clearly above. The disclosure simply fails to identify HIV-1<sub>ELI</sub> variants with the claimed genotypes/phenotypes.

5. Claims 35-40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claimed invention is directed toward purified HIV-1<sub>ELI</sub> envelope variants that differ in at least one amino acid residue from a number of other prototypical HIV-1 isolates (e.g., IIIB, BRU, or ARV-2) in the specified locations. The disclosure describes the isolation, cloning, and characterization of a novel HIV-1 isolate designated HIV-1<sub>ELI</sub>. Thus, the skilled artisan would reasonably conclude that applicants were in possession of this particular isolate. The disclosure does not describe the isolation and characterization of any other ELI variants, particularly those with

the recited genetic variation. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of other ELI variants at the time of filing.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of HIV-1<sub>ELI</sub> envelope variants. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39

U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and

knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

5       As noted *supra*, the disclosure fails to provide a partial or complete nucleotide sequence of any HIV-1<sub>ELI</sub> envelope variant having the recited properties. While the disclosure provides the complete nucleotide and amino acid sequence of a single isolate, it fails to provide any data from any other variant. Moreover, considering the  
10       quasispecies nature of HIV-1, it would be extremely difficult for the skilled artisan to envisage any particular structure for any given variant. In fact, the skilled artisan could not reasonably predict what the final structure of any given variant would be. Applicants have provided a single isolate and are now attempting to  
15       obtain protection for isolates they have neither isolated nor characterized, which is clearly inconsistent with the law. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants argue that the disclosure provides a  
20       sufficient written description of the claimed invention. This argument is not deemed to be persuasive for the reasons set forth *supra*.

6. The previous rejection of claims 35-40 under 35 U.S.C. § 112,  
25       first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, is hereby withdrawn in response to applicants' arguments.

30

***Finality of Office Action***

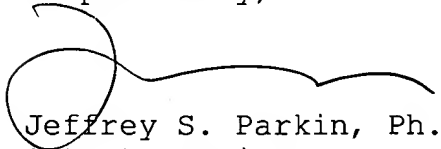
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the

extension of time policy as set forth in 37 C.F.R. § 1.136(a). A  
SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET  
TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT  
A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF  
THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER  
THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE  
SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY  
ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.  
§ 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY  
ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE  
LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

*Correspondence*

8. Correspondence related to this application may be submitted to  
Group 1600 by facsimile transmission. The faxing of such papers  
must conform with the notice published in the Official Gazette,  
1096 OG 30 (November 15, 1989). Official communications should be  
directed toward the following Group 1600 fax number: (703) 872-  
9306. Any inquiry concerning this communication should be directed  
to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-  
2227. The examiner can normally be reached Monday through Thursday  
from 8:30 AM to 6:00 PM. A message may be left on the examiner's  
voice mail service. If attempts to reach the examiner are  
unsuccessful, the examiner's supervisors, Laurie Scheiner or James  
Housel, can be reached at (703) 308-1122 or (703) 308-4027,  
respectively. Any inquiry of a general nature or relating to the  
status of this application should be directed to the Group 1600  
receptionist whose telephone number is (703) 308-0196.

Respectfully,

  
Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

14 November, 2003

  
LAURIE SCHEINER  
PRIMARY EXAMINER